

REMARKS

I. Status Summary

Claims 44, 47, 48, 51-54, and 56-58 are pending in the current application and have been examined and appealed to the Board of Patent Appeals and Interferences (hereinafter "the Board"). The following rejections have been affirmed by the Board:

- (A) the enablement rejection of claims 53 and 54;
- (B) the anticipation rejection of claims 44, 47, 48, 52, and 56 over Chang (1995)
19 Cell Biol Intl 143-149 (hereinafter "Chang 1995");
- (C) the anticipation rejection of claims 44, 47, 48, 52, and 56 over Chang (1997)
21 Cell Biol Intl 495-499 (hereinafter "Chang 1997"); and
- (D) the obviousness rejection of claims 44, 47, 48, 52, and 58 over Chang 1995 and U.S. Patent No. 6,156,569 to Ponce de Leon (hereinafter the "Ponce de Leon '569 Patent").

Claims 51, 56, and 57 have been canceled without prejudice.

Claim 44 has been amended. Support for the amendments can be found throughout the specification of the application as filed, including particularly at page 13, lines 11-12 (BRL conditioned medium). Additional support for the amendments can be found at page 15, lines 10-22 and at page 17, lines 4-15 (undifferentiated avian cells are embryonic stem cells); and at page 4, lines 15-17; at page 12, lines 3-4; and in Figures 1-4 and their accompanying descriptions beginning on page 5, line 16 and continuing through page 7, line 24 (use of STO cells as feeder matrix). Thus, no new matter has been added by virtue of the claim amendments. Reconsideration of the application as amended and based on the remarks set forth below is respectfully requested.

II. The Rejection under 35 U.S.C. § 112, First Paragraph

The rejection of claims 53 and 54 under the enablement provision of 35 U.S.C. § 112, first paragraph, has been affirmed by the Board. According to the Board in the Decision on Appeal dated February 25, 2008 (hereinafter the "Decision on Appeal"), the claims "require one month or more of culture while retaining the embryonic stem cell phenotype, but there are no working examples of culture beyond five days, no guidance in the Specification on culture for more than five days and the prior art supports the

conclusion that such culture of cells retaining an embryonic stem cell phenotype requires a large quantity of unpredictable experimentation".

After careful consideration of the rejection and the Board's position with respect thereto, applicants respectfully traverse the rejection and submit the following remarks.

Applicants respectfully submit that as acknowledged by the Board, the specification as filed discloses that "[t]he avian embryo cells of the present invention can be cultured for at least one or two months as is typical for a primary cell culture, which is significantly greater than the usual two week life of primary cultures of cells from an unincubated avian embryo (Spec. 14, II. 4-7)". See Finding of Fact (FF) 12, page 11 of the Decision on Appeal. Applicants further respectfully submit that the Board acknowledged that "[g]onadal cells were cultured on STO feeder layers for 3-5 days and stained with anti-SSEA-1. The number of single SSEA-1 positive PGCs and the number of SSEA-1 positive colonies were examined at day 0, 1, 3 and 5 of culture (Spec. 20, II. 10-13)". See FF10, page 11 of the Decision on Appeal.

Applicants further respectfully submit that the Specification as filed discloses that "[t]he media [employed] may be a conditioned media or a synthetic media, both of which are known in the art. Conditioned media, and particularly BRL conditioned media, is currently preferred". See Specification at page 13, lines 10-12 (emphasis added). Claim 44 has been amended to recite *inter alia* that the sustained cultures comprise BRL conditioned medium. Support for the amendment can be found throughout the specification as filed, including particularly at page 13, lines 10-12.

Furthermore, applicants respectfully submit that the Specification as filed discloses that the feeder matrix may comprise fibroblast cells, preferably mouse fibroblast cells, and more preferably mouse STO fibroblast cells. See Specification at page 4, lines 10-17. Claim 44 has also been amended to recite that the preconditioned feeder matrix is a preconditioned STO feeder matrix.

Therefore, applicants respectfully submit that upon review of the instant specification, one of ordinary skill in the art would understand the instant disclosure to teach, for example, culturing chicken primordial germ cells (PGCs) and chicken stromal cells that are isolated together from the embryonic genital ridge or gonad from a chicken embryo at a stage later than stage 14 according to the Hamburger & Hamilton staging

system, on a preconditioned STO feeder matrix in Buffalo Rat Liver (BRL) conditioned media. Applicants further respectfully submit that when the chicken primordial germ cells (PGCs) are cultured on a preconditioned STO feeder matrix in Buffalo Rat Liver (BRL) conditioned media, they acquire the recited embryonic stem cell phenotype. In fact, applicants respectfully submit that they have surprisingly found that when the later than stage 14 chicken PGCs are cultured on STO feeders in this medium, undifferentiated chicken cells expressing an embryonic stem cell phenotype are generated, and further that the undifferentiated chicken cells expressing an embryonic stem cell phenotype so generated maintain the embryonic stem cell phenotype for at least one or two months as set forth in claims 53 and 54.

As such, applicants respectfully submit that with the amendments to claim 44 to recite a particular conditioned medium and feeder cells, the basis upon which the Patent Office has rejected claims 53 and 54 and upon which the Board maintained this rejection, namely the breadth of the claims with respect to the culture conditions, has been addressed. As a result, applicants respectfully submit that claims 53 and 54 fully comply with the requirements of the enablement provision of 35 U.S.C. § 112 first paragraph.

III. The Rejection under 35 U.S.C. § 102(b) over Chang 1995

Claims 44, 47, 48, 52, and 56 have been rejected under 35 U.S.C. § 102(b) over Chang 1995. Applicants have amended claim 44 to recite that the sustained culture comprises BRL conditioned medium and a preconditioned STO feeder matrix. Applicants respectfully submit that Chang 1995 does not disclose use of BRL conditioned medium or a preconditioned STO feeder matrix.

Accordingly, applicants respectfully submit that Chang 1995 does not disclose each and every element of claim 44, and thus does not support a rejection of claim 44 under 35 U.S.C. § 102(b). Further, applicants respectfully submit that claims 47, 48, 52, and 56 all depend directly or indirectly from claim 44, and thus are also believed to be distinguished over Change 1995. As a result, applicants respectfully submit that claims 44, 47, 48, 52, and 56 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

IV. The Rejection under 35 U.S.C. § 102(b) over Chang 1997

Claims 44, 47, 48, 52, and 56 have been rejected under 35 U.S.C. § 102(b) over Chang 1997. As set forth hereinabove, applicants have amended claim 44 to recite that the sustained culture comprises BRL conditioned medium and a preconditioned STO feeder matrix. Applicants respectfully submit that like Chang 1995, Chang 1997 does not disclose the use of BRL conditioned medium or a preconditioned STO feeder matrix.

Accordingly, applicants respectfully submit that Chang 1997 does not disclose each and every element of claim 44, and thus does not support a rejection of claim 44 under 35 U.S.C. § 102(b). Further, applicants respectfully submit that claims 47, 48, 52, and 56 all depend directly or indirectly from claim 44, and thus are also believed to be distinguished over Change 1997. As a result, applicants respectfully submit that claims 44, 47, 48, 52, and 56 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

V. The Rejection under 35 U.S.C. § 103(a)

Claims 44, 47, 48, 52, and 58 have been rejected under 35 U.S.C. § 103(a) over Chang 1995 and the Ponce de Leon '569 Patent. According to the Board, claims 44, 47, 48, and 52 are obvious over this combination because they are anticipated by Chang 1995. Thus, the Board provides no additional discussion with respect to the obviousness of these claims apart from the fact that Chang 1995 allegedly discloses all of the elements of the claim.

After careful consideration of the rejection and the Board's position with respect thereto, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that claim 44 has been amended to recite a sustained culture comprising *inter alia* BRL conditioned medium and a preconditioned STO feeder matrix. Applicants respectfully submit that neither Chang 1995 nor the Ponce de Leon '569 Patent teaches employing either of these components. In fact, applicants respectfully submit that these elements had been recited in claims 51 and 57, respectively. In the Examiner's Answer dated April 11, 2007, the rejections under 35 U.S.C. § 103(a) of claims 51 and 57 over the combination of Chang 1995 and the Ponce de Leon '569 Patent was withdrawn. See Examiner's Answer at page 24.

Accordingly, it is believed that the amendments to claim 44 that incorporate the elements of pending claims 51 and 57 directly into claim 44 distinguish claim 44 over the combination of Chang 1995 and the Ponce de Leon '569 Patent. Furthermore, claims 47, 48, 52, and 58 all depend directly or indirectly from claim 44, and thus are also believed to be distinguished over the combination of Chang 1995 and the Ponce de Leon '569 Patent. As such, applicants respectfully request that the rejection of claims 44, 48, 52, and 58 over the combination of Chang 1995 and the Ponce de Leon '569 Patent be withdrawn at this time.

CONCLUSION

In light of the amendments and remarks presented herein, applicants respectfully submit that claims 44, 47, 48, 52-54, and 58 are now in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

If any minor issues should remain outstanding after the Examiner has had an opportunity to study the Amendment and Remarks, it is respectfully requested that the Examiner telephone the undersigned attorney so that all such matters may be resolved and the application placed in condition for allowance without the necessity for another Action and/or Amendment.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any deficiencies of payment or credit any overpayments associated with the filing of this Amendment After Final to Deposit Account No. 50-0426.

Respectfully submitted,

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